

(d) *What circumstances and information can establish good cause for a reduction in the discontinuance notification period?*

(1) A public health problem may result from continuation of manufacturing for the 6-month period. This certification must include a detailed description of the potential threat to the public health.

(2) A biomaterials shortage prevents the continuation of the manufacturing for the 6-month period. This certification must include a detailed description of the steps taken by the applicant in an attempt to secure an adequate supply of biomaterials to enable manufacturing to continue for the 6-month period and an explanation of why the biomaterials could not be secured.

(3) A liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period. This certification must include a detailed description of the potential liability problem.

(4) Continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer. This certification must include a detailed description of the financial impact of continuing to manufacture the drug product over the 6-month period.

(5) The manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code (11 U.S.C. 701 *et seq.* and 1101 *et seq.*). This certification must be accompanied by documentation of the filing or proof that the filing occurred.

(6) The manufacturer can continue distribution of the drug product to satisfy existing market need for 6 months. This certification must include a detailed description of the manufacturer's processes to ensure such distribution for the 6-month period.

(7) Other good cause exists for the reduction. This certification must include a detailed description of the need for a reduction.

[72 FR 58999, Oct. 18, 2007]

Subpart C—Abbreviated Applications

SOURCE: 57 FR 17983, Apr. 28, 1992, unless otherwise noted.

§ 314.92 Drug products for which abbreviated applications may be submitted.

(a) Abbreviated applications are suitable for the following drug products within the limits set forth under § 314.93:

(1) Drug products that are the same as a listed drug. A “listed drug” is defined in § 314.3. For determining the suitability of an abbreviated new drug application, the term “same as” means identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use, except that conditions of use for which approval cannot be granted because of exclusivity or an existing patent may be omitted. If a listed drug has been voluntarily withdrawn from or not offered for sale by its manufacturer, a person who wishes to submit an abbreviated new drug application for the drug shall comply with § 314.122.

(2) [Reserved]

(3) Drug products that have been declared suitable for an abbreviated new drug application submission by FDA through the petition procedures set forth under § 10.30 of this chapter and § 314.93.

(b) FDA will publish in the list listed drugs for which abbreviated applications may be submitted. The list is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, 202-783-3238.

[57 FR 17983, Apr. 28, 1992, as amended at 64 FR 401, Jan. 5, 1999]

§ 314.93 Petition to request a change from a listed drug.

(a) The only changes from a listed drug for which the agency will accept a petition under this section are those changes described in paragraph (b) of this section. Petitions to submit abbreviated new drug applications for other changes from a listed drug will not be approved.

(b) A person who wants to submit an abbreviated new drug application for a drug product which is not identical to a listed drug in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug, must